

MEDICATION GUIDE
Bexagliflozin (bex" a gli floe' zin) Tablets
for oral use

What is the most important information I should know about bexagliflozin tablets?

Bexagliflozin tablets can cause serious side effects, including:

- **Diabetic Ketoacidosis (increased ketones in your blood or urine) in people with type 1 diabetes and other ketoacidosis.** Bexagliflozin tablets can cause ketoacidosis that can be life-threatening and may lead to death. Ketoacidosis is a serious condition which needs to be treated in a hospital. People with type 1 diabetes have a high risk of getting ketoacidosis. People with type 2 diabetes or pancreas problems also have an increased risk of getting ketoacidosis. Ketoacidosis can also happen in people who: are sick, cannot eat or drink as usual, skip meals, are on a diet high in fat and low in carbohydrates (ketogenic diet), take less than the usual amount of insulin or miss insulin doses, drink too much alcohol, have a loss of too much fluid from the body (volume depletion), or who have surgery. Ketoacidosis can happen even if your blood sugar is less than 250 mg/dL. Your healthcare provider may ask you to periodically check ketones in your urine or blood.
Stop taking bexagliflozin tablets and call your healthcare provider or get medical help right away if you get any of the following. If possible, check for ketones in your urine or blood, even if your blood sugar is less than 250 mg/dL.

- nausea
- vomiting
- stomach-area (abdominal) pain
- tiredness
- trouble breathing
- ketones in your urine or blood

- **Amputations.** Bexagliflozin tablets may increase your risk of lower limb amputations. Amputations mainly involve removal of the toe or part of the foot, however, amputations involving the leg, below and above the knee, have also occurred. Some people had more than one amputation.

You may be at a higher risk of lower limb amputation if you:

- have a history of amputation
- have heart disease or are at risk for heart disease
- have had blocked or narrowed blood vessels, usually in your leg
- have damage to the nerves (neuropathy) in your leg
- have had diabetic foot ulcers or sores

Call your healthcare provider right away if you have new pain or tenderness, any sores, ulcers, or infections in your leg or foot. Your healthcare provider may decide to stop your bexagliflozin tablets for a while if you have these signs or symptoms. Talk to your healthcare provider about proper foot care.

- **Dehydration.** Bexagliflozin tablets can cause some people to become dehydrated (the loss of body water and salt). Dehydration can make you feel dizzy, faint, light-headed, or weak, especially when you stand up (orthostatic hypotension). There have been reports of sudden worsening of kidney function in people who are taking bexagliflozin tablets.

You may be at higher risk of dehydration if you:

- take medicines that lower your blood pressure, including diuretics (water pills)
- are on a low sodium (salt) diet
- have kidney problems
- are 65 years of age or older

Talk to your healthcare provider about what you can do to prevent dehydration including how much fluid you should drink on a daily basis. Call your healthcare provider right away if you reduce the amount of food or liquid you drink, for example if you are sick or cannot eat, or start to lose liquids from your body, for example from vomiting or diarrhea.

- **Vaginal yeast infection.** Women who take bexagliflozin tablets may get vaginal yeast infections. Yeast infections can be a serious but common side effect of taking bexagliflozin tablets. Symptoms of a vaginal yeast infection include:

- vaginal odor
- white or yellowish vaginal discharge (discharge may be lumpy or look like cottage cheese)
- vaginal itching

- **Yeast infection of the penis (balanitis or balanoposthitis).** Men who take bexagliflozin tablets may get a yeast infection of the skin around the penis. Men who are not circumcised may have swelling of the penis that makes it difficult to pull back the skin around the tip of the penis. Other symptoms of yeast infection of the penis include:

- redness, itching, or swelling of the penis
- rash of the penis
- foul smelling discharge from the penis
- pain in the skin around penis

Talk to your healthcare provider about what to do if you get symptoms of a yeast infection of the vagina or penis. Your healthcare provider may suggest you use an over-the-counter antifungal medicine. Talk to your healthcare provider as soon as possible if you use an over-the-counter antifungal medication and your symptoms do not go away.

What is bexagliflozin?

- Bexagliflozin is a prescription medicine used along with diet and exercise to improve blood sugar (glucose) in adults with type 2 diabetes.
- Bexagliflozin is not recommended to decrease blood sugar in people with type 1 diabetes.
- It is not known if bexagliflozin is safe and effective in children under 18 years of age.

Do not take bexagliflozin tablets if you:

- are allergic to bexagliflozin or any of the ingredients in bexagliflozin tablets. See the end of this Medication Guide for a list of ingredients in bexagliflozin tablets. Symptoms of a serious allergic reaction to bexagliflozin tablets may include:
 - skin rash
 - raised red patches on your skin (hives)
 - swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing

Before you take bexagliflozin tablets, tell your healthcare provider about all of your medical conditions, including if you:

- have type 1 diabetes or have had diabetic ketoacidosis
- have a decrease in your insulin dose
- have a serious infection
- have a history of infection of the vagina or penis
- have a history of amputation
- have had blocked or narrowed blood vessels, usually in your leg
- have damage to the nerves (neuropathy) in your leg
- have had diabetic foot ulcers or sores
- have kidney problems
- have liver problems
- have a history of urinary tract infections or problems with urination
- have or have had problems with your pancreas, including pancreatitis or surgery on your pancreas
- are on a low sodium (salt) diet. Your healthcare provider may change your diet or your dose.
- are going to have surgery. Your healthcare provider may stop your bexagliflozin tablets before you have surgery. Talk to your healthcare provider if you are having surgery about when to stop taking bexagliflozin tablets and when to start it again.
- are eating less or there is a change in your diet
- are dehydrated
- drink alcohol very often or drink a lot of alcohol in the short term ("binge" drinking).
- have ever had an allergic reaction to bexagliflozin tablets
- are pregnant or planning to become pregnant. Bexagliflozin may harm your unborn baby. If you become pregnant while taking bexagliflozin tablets, tell your healthcare provider as soon as possible. Talk with your healthcare provider about the best way to control your blood sugar while you are pregnant.
- are breastfeeding or plan to breastfeed. Bexagliflozin may pass into your breast milk and may harm your baby. Talk with your healthcare provider about the best way to feed your baby if you take bexagliflozin tablets. Do not breastfeed while taking bexagliflozin tablets.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Bexagliflozin tablets may affect the way other medicines work, and other medicines may affect how bexagliflozin tablets work. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take bexagliflozin tablets?

- Take bexagliflozin tablets exactly as your healthcare provider tells you to take it.
- Take bexagliflozin tablets by mouth 1 time in the morning, with or without food.
- Do not crush or chew bexagliflozin tablets.
- Your healthcare provider may tell you to take bexagliflozin tablets along with other diabetes medicines. Low blood sugar can happen more often when bexagliflozin tablets are taken with certain other diabetes medicines. See "What are the possible side effects of bexagliflozin tablets?"
- If you miss a dose, take it as soon as you remember. If it is time for your next dose, skip the missed dose and take the medicine at the next regularly scheduled time. Do not take 2 doses of bexagliflozin tablets at the same time. Talk with your healthcare provider if you have questions about a missed dose.
- If you take too many bexagliflozin tablets, call your healthcare provider or go to the nearest hospital emergency room right away.
- When your body is under some types of stress, such as fever, trauma (such as a car accident), infection, fasting, binge drinking or surgery, the amount of diabetes medicine that you need may change. Tell your healthcare provider as soon as possible if you have any of these conditions and follow your healthcare provider's instructions.
- Bexagliflozin tablets will cause your urine to test positive for glucose.
- Your healthcare provider may do certain blood tests before you start bexagliflozin tablets and during treatment as needed. Your healthcare provider may change your dose of bexagliflozin tablets based on the results of your blood tests.

What are the possible side effects of bexagliflozin?

Bexagliflozin tablets may cause serious side effects, including:

- See "What is the most important information I should know about bexagliflozin?"
- **serious urinary tract infections.** Serious urinary tract infections that may lead to hospitalization have happened in people who are taking bexagliflozin tablets. Tell your healthcare provider if you have signs or symptoms of a urinary tract infection such as a burning feeling when passing urine, a need to urinate often, the need to urinate right away, pain in the lower part of your stomach (pelvis), or blood in the urine. Sometimes people also may have a fever, back pain, nausea or vomiting.
- **low blood sugar (hypoglycemia).** If you take bexagliflozin tablets with another medicine that can cause low blood sugar such as a sulfonylurea or insulin, your risk of getting low blood sugar is higher. The dose of your sulfonylurea or insulin may need to be lowered while you take bexagliflozin tablets. Signs or symptoms of low blood sugar may include:
 - headache
 - confusion
 - hunger
 - shaking or feeling jittery
 - drowsiness
 - dizziness
 - fast heartbeat
 - weakness
 - sweating
 - irritability
- **a rare but serious bacterial infection that causes damage to the tissue under the skin (necrotizing fasciitis) in the area between and around the anus and genitals (perineum).** Necrotizing fasciitis of the perineum has happened in people who take bexagliflozin tablets. Necrotizing fasciitis of the perineum may lead to hospitalization, may require multiple surgeries, and may lead to death. **Seek medical attention immediately if you have fever or you are feeling very weak, tired or uncomfortable (malaise) and you develop any of the following symptoms in the area between and around your anus and genitals:**
 - pain or tenderness
 - swelling
 - redness of the skin (erythema)
- **Serious allergic reaction.** If you have any symptoms of a serious allergic reaction, stop taking bexagliflozin tablets and call your healthcare provider right away or go to the nearest hospital emergency room. See "**Do not take bexagliflozin tablets if you:**". Your healthcare provider may give you a medicine for your allergic reaction and prescribe a different medicine for your diabetes.

The most common side effects of bexagliflozin tablets include:

- vaginal yeast infections
- urinary tract infections
- changes in urination, including urgent need to urinate more often, in larger amounts, or at night.

These are not all the possible side effects of bexagliflozin tablets. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store bexagliflozin tablets?

Store bexagliflozin tablets at room temperature between 68 °F to 77 °F (20 °C to 25 °C).

Keep bexagliflozin tablets and all medicines out of the reach of children.

General information about the safe and effective use of bexagliflozin tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use bexagliflozin tablets for a condition for which it was not prescribed. Do not give bexagliflozin tablets to other people, even if they have the same symptoms you have. It may harm them. You can ask your pharmacist or healthcare provider for information about bexagliflozin tablets that is written for health professionals.

What are the ingredients in bexagliflozin tablets?

Active ingredient: bexagliflozin

Inactive ingredients: colloidal silicon dioxide, glyceryl dibehenate, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene oxide, and poloxamer 188. In addition, the film coating ingredient, Opadry® II Blue 85F99153, contains the inactive ingredients FD&C Blue #1/Brilliant Blue FCF and FD&C Blue #2/Indigo Carmine, macrogol 3350, polyvinyl alcohol, talc, and titanium dioxide.

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For medical information about bexagliflozin tablets, call 1-855-273-6928.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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